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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,970	08/04/2003	Satishchandra P. Patel	M0025.0293/P0293	4466

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EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,970	PATEL, SATISHCHANDRA P.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites the monoester makes up less than 60% of the mixture. According to the teaching in the prior art, Mulye (US 6,436,430), when carrier system contained propylene glycol ester having greater percentage of diester in the mixture with monoester, the system lacks uniformity, and is not suitable for any commercial use (column 15, lines 45 through column 16, lines 1-44).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." In *In re Wands*, these factors include:

- 1) The nature of the invention;
- 2) The state of the prior art;
- 3) The level of one of ordinary skill;
- 4) The level of predictability in the art;

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5) The breadth of the claims;

6) The amount of direction or guidance provided by the inventor;

7) The existence of working examples; and

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation. These factors are discussed in detailed as follow:

1) The nature of the invention: the invention is directed to a composition comprising a homogeneous solution of cyclosporine which on exposure to water forms an emulsion.

2) The state of the prior art: the state of the art is very high.

3) The level of one of ordinary skill: the ordinary skill in the art is high (MD or PhD level technology).

4) The level of predictability in the art: there is predictability in the art of the ability of self-emulsifying cyclosporine composition.

5) The breadth of the claims: instant independent claim is broad.

6) The amount of direction or guidance provided by the inventor: not clear. Table 2 in applicant's specification showing examples 1-3 containing either mono- or diester of propylene glycol. The table confirms that the composition does not require mixture of mono- and diester propylene glycol. Only example 4 discloses mixture of the two, but does not clearly point out which one is which. Thus, it is unclear which propylene glycol

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is 130 weight/mg or 76.5%. The example further does not disclose any unexpected and/or unusual results over the mixture of mono- and diester propylene glycol. Table 3 comparing showing comparison data, but again, does not require mixture of both. In contrast to the present invention, the prior art, Mulye, shows that when the pharmaceutical formulation contained the diester propylene glycol greater than 50%, the formulation lacks uniformity, and therefore, is not suitable for any commercial use (column 15, lines 44-56). Accordingly, the amount of direction or guidance provided by the inventor is unclear, and insufficient.

7) The existence of working examples: there is one working example, however, it fails to show any significant results over the mixture of mono- and diester propylene glycol.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: it would require an undue experimentation by one of ordinary skill in the art to determine the significant differences between the claimed chewing gum and those that do not contain the claimed acid and acid salts.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye WO 00/33862.

Mulye teaches a self-emulsifying composition comprising 0.01-50% cyclosporine, nonionic surfactant having HLB greater than 10, and mixture of fatty acids such as propylene glycol ester having at least about 60% by weight monoesters based on the total weight of the propylene glycol ester (abstract; page 14; pages 16, lines 28 through page 17, lines 1-9; and page 20). The composition is suitable for drinking solution, and hard/soft gelatin capsule formulations (page 23, lines 21 through page 24, lines 1-6). The composition further comprises antioxidants such as tocopherol, BHA, BHT, and the like (page 21, lines 20-27).

Mulye does not explicitly teach mixture of mono- and diester propylene glycol. However, Mulye teaches mixture of propylene glycol maybe use. Thus, it would have been obvious to one of ordinary skill in the art to include diester propylene glycol in the mixture, because Mulye does not exclude the use of diester propylene glycol, because Mulye teaches mixture of fatty acids contain 60% of monoester propylene glycol (page 16), and because Mulye only exclude the present of triglycerides.

#### Pertinent Arts

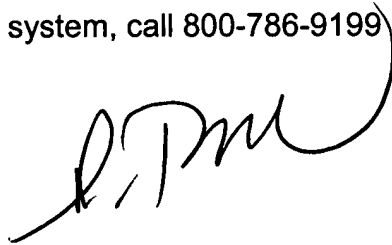
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Linn is cited as of interest for the teaching of carrier system for cyclosporine.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm; Thurs. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to be 'S. Tran', with a large, sweeping loop at the end.

S. Tran  
Primary Examiner  
Art Unit 1615